

# INSTRUCTIONS FOR USE FOR:



C A R D I O V A S C U L A R P A T C H

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es

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se

Svenska

## INSTRUCTIONS FOR USE FOR GORE ACUSEAL Cardiovascular Patch

### INDICATIONS

FOR USE IN CARDIOVASCULAR PATCHING.

### CONTRAINDICATIONS

THERE ARE NO KNOWN CONTRAINDICATIONS.

### STERILITY

The GORE ACUSEAL Cardiovascular Patch is supplied **STERILE** unless the package has been opened or damaged. Provided that the integrity of the package is not compromised in any way, it will serve as an effective barrier until the "use by" (expiration) date printed on the box.

### RECOMMENDED TECHNIQUES

#### HANDLING

To open the package, hold the base of the tray and peel back the lid so that the inner tray can be removed by grasping the sealed lip. Beginning at one corner, peel back the inner tray lid and gently remove the GORE ACUSEAL Cardiovascular Patch. Use clean gloves or atraumatic instruments when handling the GORE ACUSEAL Cardiovascular Patch. It is not necessary to preclot the GORE ACUSEAL Cardiovascular Patch.

Infrequently, upon removal from the package, wrinkles may be evident on the GORE ACUSEAL Cardiovascular Patch. To soften the material or to remove the wrinkles, immerse the patch in warm (> 34° C / 93° F) sterile liquid (i.e., water, saline solution) for one minute (or until wrinkles relax).

#### SIZING

Trim the GORE ACUSEAL Cardiovascular Patch to the desired size using a scalpel or sharp surgical scissors. **Cutting to proper size is essential.** Cutting the GORE ACUSEAL Cardiovascular Patch too small may result in excessive tension on the suture line, which may contribute to suture line bleeding. Do not use GORE ACUSEAL Cardiovascular Patches together to form a larger patch. This is not part of the design criteria of this product and may result in a mechanically inadequate repair.

#### SUTURING

**Do not use absorbable suture. Use only nonabsorbable suture**, such as GORE-TEX® Suture, with a noncutting needle (such as taper or piercing point) of appropriate size. For best results, use monofilament sutures. Surgeon preference and the nature of the reconstruction should determine suture size.

Use a **minimum 2 mm suture bite** in cardiac and great vessel applications. For peripheral applications, use a minimum 1 mm suture bite.

**In cardiovascular reconstructions, suture line bleeding may be attributed to various sources, such as:**

- gaps between the prosthetic material and the native tissue
- suture holes in the prosthetic material
- suture holes in the native tissue
- patient coagulopathy or platelet dysfunction

Significant suture line bleeding may occur if suture holes are elongated, torn, or if large gaps are allowed to form between the prosthetic material and the native tissue. Use appropriate suture size and placement to prevent gaps. To minimize suture hole bleeding, use minimal tension when pulling up on the suture line or when placing a knot. Use the smallest needle that is appropriate for the repair. Follow the curve of the needle through the GORE ACUSEAL Cardiovascular Patch to avoid damaging the material and enlarging the suture holes. Topical hemostatic agents may be used to minimize anastomotic bleeding. The manufacturers' instructions for these hemostatic products should be observed.

### VASCULAR ACCESS

When using the GORE ACUSEAL Cardiovascular Patch for vascular access applications or where repeated needle punctures of the patch may be necessary, ensure that needle puncture sites are evenly spaced apart along the accessible subcutaneous length of the patch. Repeated needle puncture of the GORE ACUSEAL Cardiovascular Patch at the same site, or within the same immediate area, may cause mechanical damage to the GORE ACUSEAL Cardiovascular Patch which could lead to hematoma or false aneurysm formation. Patients should be carefully monitored.

### WARNINGS

#### NOT FOR RECONSTRUCTION OF:

- HERNIAS
  - SOFT TISSUE DEFICIENCIES
  - PASSIVE BIOLOGICAL MEMBRANES SUCH AS DURA MATER, PERICARDIUM, OR PERITONEUM
- Use of this product in applications other than those indicated has the **potential for serious complications**, such as suture pullout, failure of the repair, or undesired healing to surrounding tissues.
- Preclinical animal studies suggest that tissue ingrowth may be enhanced in this patch as compared to ePTFE alone. Clinical experience with this material is currently unavailable.

## PRECAUTIONS

- **Do not take less than a 2 mm** suture bite in all cardiac and great vessel applications.
- **Do not take less than a 1 mm** suture bite in all peripheral applications.
- **Do not** use absorbable sutures.
- **Do not** use a cutting needle.
- **Do not** handle with ungloved hands.
- **Do not** cut the patch too small.
- **Do not** sew two patches together.
- **Do not** place excessive tension on the suture line.
- **Do not** puncture the patch repeatedly at the same site or within the same immediate area.
- **Do not** contaminate or damage the patch.
- **Do not** allow the GORE ACUSEAL Cardiovascular Patch to contact organic fluids such as alcohol or BETADINE® solution.

## POSSIBLE COMPLICATIONS WITH THE USE OF ANY CARDIOVASCULAR PROSTHESIS

Complications that may occur include, but are not limited to; infection, inflammation, perigraft seroma formation, hematomas, thrombosis, prolonged bleeding, or formation of pseudoaneurysms.

## RESTERILIZATION

The GORE ACUSEAL Cardiovascular Patch may be resterilized up to three times using steam techniques without compromising its mechanical or structural quality. Do not sterilize the GORE ACUSEAL Cardiovascular Patch in the original packaging materials. The GORE ACUSEAL Cardiovascular Patch must be repackaged in materials appropriate for sterilization. Sterility of repackaged product is the responsibility of the health care institution.

Clean, unused, and undamaged portions of the GORE ACUSEAL Cardiovascular Patch may be resterilized if handled with clean gloves or atraumatic instruments such as dry transfer forceps. Protect the GORE ACUSEAL Cardiovascular Patch from heavy or sharp objects during sterilization.

- Do not expose the GORE ACUSEAL Cardiovascular Patch to temperatures greater than 482 °F (250 °C).
- Do not sterilize the GORE ACUSEAL Cardiovascular Patch using radiation.

## STEAM

Using a validated gravity displacement steam sterilizer, autoclave at or above these minimum requirements: 250 °F (121 °C) for 30 minutes or 270 °F (132 °C) for 15 minutes.

Using a validated pre-vacuum (also known as high vacuum) steam sterilizer, autoclave at or above these minimum requirements: 270°F (132°C) for 4 minutes.

## FOR OTHER PATCHING APPLICATIONS

The GORE DUALMESH® Biomaterial, GORE MYCROMESH® Biomaterial and GORE-TEX® Soft Tissue Patch are available for the reconstruction of hernias and soft tissue deficiencies.

The GORE PRECLUDE® Pericardial Membrane is available for reconstruction or repair of the pericardium.

## DEFINITIONS



Use By



Attention, See Instructions for Use



Do Not Re-Use

**REF** Catalogue Number

**LOT** Batch Code

**EC|REP** European Authorized Representative

**STERILE**

Contents sterile unless package has been opened or damaged.

**STERILE** ↓

Contents sterile unless enclosed package has been opened or damaged. Sterilized by steam.



AB0687-ML4



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